UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,236	03/11/2004	Abhay Sharma	U 015074-0	3561

7590 01/17/2008

Ladas & Parry
26 West 61 Street
New York, NY 10023

EXAMINER	
PERREIRA, MELISSA JEAN	
ART UNIT	**PAPER NUMBER**
1618	

MAIL DATE	DELIVERY MODE
01/17/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/798,236	SHARMA, ABHAY	
	Examiner	Art Unit	
	Melissa Perreira	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 5-9 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 5-9 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/26/07 has been entered.

Priority

2. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in WIPO on 12/29/03. It is noted, however, that applicant has not filed a certified copy of the patent application as required by 35 U.S.C. 119(b). The foreign priority document was also not found on the WIPO website.

Claims and Previous Rejection Status

3. Claims 5-9 are pending in the application.

4. The rejections under 35 U.S.C. 112, second paragraph are withdrawn due to the amendment to the claims.

5. The rejection of claims 5-9 under 35 U.S.C. 103(a) as being unpatentable over Sharma et al. (US 6,541,193B2) in view of Wolf et al. (*J. Neuroscience* **2002**, *22*,

11035-11044) and Faeldt et al. (US 2004/0076583A1) as stated in the previous office action mailed 4/23/07 is modified and maintained.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 5-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sharma et al. (US 6,541,193B2) in view of Wolf et al. (*J. Neuroscience* **2002**, *22*, 11035-11044) and Faeldt et al. (US 2004/0076583A1) and further in view of Saba et al. (US 2003/0219782A1).

8. Sharma et al. (US 6,541,193B2) discloses the method for screening of neuroactive drugs using the fruit fly *Drosophila melanogaster* (abstract; column 1, lines 62-64) with the first step being the culturing of flies in medium under standard conditions (column 2, lines 19-20). The method involves comparing flies treated with normal fly food mixed with the agent (to be screened) to flies fed on normal fly food (column 2, lines 23-26). In one embodiment, a blind screening of plant extracts was examine via mixing the extracts with the standard fly medium (culturing medium) in vials and transferring flies to the extract containing medium where the fly culture conditions and fly manipulations used were as those described earlier (above) (column 4, lines 39-49). The cultured flies are separated in to two groups including a first group fed with normal

food and a second group fed with food mixed with an agent (phenobarbital sodium) being screened and fed for 5 more days (column 2, lines 23-26; column 3, lines 50-53). The locomotor activities of the flies fed with regular food are compared to the locomotor activities of the flies fed with food mixed with an agent where the increased locomotor activity is indicative of a psychostimulant activity of the agent (column 2, lines 39-42; column 5, line 2). Sharma et al. (US 6,541,193B2) does not disclose the specific neuroactive drugs or the specific locomotor activities of the instant claims.

9. Faeldt et al. (US 2004/0076583A1) discloses the method of screening for the effects of a test agent on a population of *Drosophila melanogaster* to monitor one or more traits, such as locomotor activity of the test agent, such as pilocarpine (p3, [0041-0042]; p7, [0076]). Two groups or more, including a first group that are administered a test agent and a second reference group, are examined and compared for their locomotor activity (p4, [0050] and [0053]). The traits/locomotor activities are measured by detecting the movement of a population of flies in containers, such as in a horizontal and vertical direction (p3, [0045]; p7, [0079]-[0088]; p8, [0104]).

10. Wolf et al. (*J. Neuroscience* **2002**, *22*, 11035-11044) discloses the analysis of the locomotor activity in *Drosophila* (p11035, paragraph 3). The examination of the locomotor activity, via walking speed (fig 2) consists of alternating the exposure of air and ethanol to the flies. The flies become immobile upon overexposure to ethanol but recover when a stream of air replaces the ethanol and the hyperactive phase caused by the smell of the ethanol is attributable to internal accumulation of ethanol affecting nervous system function is indicative of neural plasticity (p11037, paragraph 1).

11. Saba et al. (US 2003/0219782A1) discloses culturing *Drosophila melanogaster* in the absence or presence of a candidate agent under conditions and for a time sufficient to observe in the *Drosophila melanogaster* an effect of the agent (p2, [0018]).

12. At the time of the invention it would have been obvious to one ordinarily skilled in the art to screen neuroactive drugs by monitoring the locomotor activities of for *Drosophila melanogaster* as taught by Faeldt et al. and Sharma et al. Culturing of the flies in medium without or containing the drug would be obvious in light of the disclosure of Saba et al. in combination with the blind screen test of Sharma et al. as it is disclosed that the plant extracts were mixed with the standard fly medium (culturing medium) and therefore is available for culturing.

13. Wolf et al. describes the method of measuring neural plasticity via administering a psychoactive drug (ethanol) to flies and monitoring the recovery from such administration and monitoring locomotor activities. The recovery from the administration of the psychoactive drug (ethanol) via administering a stream of air meets the requirements for withdrawing the drug and subsequently measuring the locomotor activity to determine neural plasticity (long lasting alteration). One would have a reasonable expectation of success for combining the disclosures to monitor the neural plasticity induced by the (any) neuroactive drug to the flies since all experiments require monitoring the locomotor activities upon administration of such a neuroactive drug. Also, it would be obvious to one ordinarily skilled that one would choose all known and readily available neuroactive drugs, such as pilocarpine for such screening methods for an extensive range of drugs in order to obtain the most accurate and

detailed data. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Response to Arguments

14. Applicant asserts that none of the references disclose culturing flies with a media with a neuroactive drug, examining the locomotor activity of the flies, withdrawing the neuroactive drug and then again examining the locomotor activity to determine whether there is a long-lasting alteration in locomotion.

15. Culturing of the flies in medium without or containing the drug would be obvious in light of the blind screen test of Sharma et al. as it is disclosed that the plant extracts were mixed with the standard fly medium (culturing medium) and therefore is available for culturing. All of the disclosures describe the examination of locomotor activity of flies upon administration of a neuroactive drug. Wolf et al. describes the method of measuring neural plasticity via administering a psychoactive drug (ethanol) to flies and monitoring the recovery from such administration and monitoring locomotor activities. The recovery from the administration of the psychoactive drug (ethanol) via administering a stream of air meets the requirements for withdrawing the drug and subsequently measuring the locomotor activity to determine neural plasticity (long lasting alteration). At the time of the invention it would have been obvious that monitoring the recovery (withdrawing the neuroactive drug) and then subsequently

monitoring the locomotor activities (Wolf et al.) can also be used for the methods of Sharma et al. and Faeldt et al.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa Perreira whose telephone number is 571-272-1354. The examiner can normally be reached on 9am-5pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MP
January 9, 2008

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER